Class Schedule

6/20/2000
Introduction and Syllabus
History of Human Experimentation
Readings: C - I and II
SAMPLE: PROTOCOL SUMMARY, INFORMED CONSENT, COMIRB FORMS

7/11
Foundations of Current Approach to Human Subjects Protection
Ethical Principals and Theory of Informed Consent
Readings: C - III and IV
GROUP PROJECT DISCUSSION - Topics 1, 2, 3 present 15-20 minute discussion
- Topic 1: Informed Consent for Psychiatric Patients in Clinical Research
- Topic 2: Possible Conflict of Interest Issues for Industry-Sponsored Clinical Research
- Topic 3: Tissue and Blood Banking Ethical Issues in Clinical Research

7/18
Current Regulations, Issues, and Requirements
IRB System, Institutional Responsibilities, and Investigator Responsibilities
Use of Databases and Patient Confidentiality/Privacy Issues
Readings: IRB Handouts
GROUP PROJECT DISCUSSION - Topics 4, 5, 6 present 15-20 minute discussion
- Topic 4: IRB Reform Strategies in Clinical Research
- Topic 5: Patient Identifiers and Confidentiality Issues in Clinical Research
- Topic 6: Inclusion of Women and Minority Populations in Clinical Research

8/1
Case Study Debate Chaired by Dr. Milgrom
Student Case Study Written Reports Due - Please bring three copies

NOTE:
C = Ethics in Epidemiology and Clinical Research, edited by Steven S. Coughlin

University of Colorado Health Sciences Center
Ph.D. Program in Clinical Science

CLSC 7150*/1: **Ethics and Regulation in Human Subjects Review**
1 Credit Hour

Co-Directors: **Allan Prochazka, MD, MSPH**
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Date: **Summer Quarter**

Time: **Class Lectures held 7 - 9 am on selected Tuesdays**
6/20, 7/11, 7/18, 8/1

Class Location: **Denver VA Medical Center**
6/20 - DVAMC Conference Rm 5C151
7/11 - DVAMC Conference Rm 2F22
7/18 - DVAMC Basement Auditorium
8/01 - DVAMC Basement Auditorium

***IRB Meetings:** **Two NJC IRB Meetings held 11 am - 1:30 pm**
Chaired by Dr. Henry Milgrom
6/22, 7/13 (makeup 8/10)

***IRB Locations:** **To be announced**
Contact: Lori Tripp (303) 398-1657 for directions and/or room confirmation.

Course Materials: **Ethics in Epidemiology and Clinical Research**
Edited by Steven S. Coughlin
Epidemiology Resources, Inc.
Newton, Mass. 1995
ISBN 0-917227-08-5

Ethical Research in an Ethical Society: Principles, Practicalities, and Politics
Public Responsibility in Medicine and Research
December 8, 1997 Educational Materials
132 Boylston Street, Boston, MA 02116
(617) 423-4112

Video Tape Lecture Series
Three-set of tapes with Professor Lectures and Student Presentations

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Selected readings are available on the Blackboard internet program
http://bullwinkle.uchsc.edu

Materials also on reserve at UCHSC and VA libraries

Course Description

This course will provide an overview of the field of ethics in clinical research. It is designed for investigators who will be conducting research on human subjects.

Students will learn the historical background, current regulations, and IRB requirements related to human subjects protection issues.

Course Objectives

1. History: To understand the history of human subjects protection in the United States;
2. Current Regulations and Issues: To identify the current regulations and issues related to human experimentation; and
3. Informed Consent: To learn how to prepare and submit acceptable study consent forms for Institutional Review Board approval.

Grading and Policy

GRADES:

Case Study - 60%	*****Case Study - 60%
Group Projects - 30%	*****Group Projects - 20%
Class Participation - 10%	*****Class Participation - 20%
Total - 100%	*****Total - 100%

CASE STUDY:

The purpose of the case study is to give students exposure to evaluating ethical issues for a controversial research trial involving human subjects. For this Summer 2000 assignment, each student will critically review the NEJM article by Quinn et. al. titled, "Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type I." (A sub-set of this article is available on the Blackboard on-line program.)

As primary assignment, students should evaluate the ethical issues of this case study based on the information that would have been available at the start of the study -- as if it were actually being reviewed by the IRB at that time. As a supplement to this primary assignment, students should then evaluate the ethical issues at the time the study was published. Thus, a two-phase analysis is required.

For this review, students are strongly encouraged to consider using a selected theoretical framework from the class readings (such as the ethical principles presented in the Belmont Report). Where appropriate, students should explore alternative study design approaches that may be used by these investigators to address the ethical issues raised. As necessary, students should gather additional literature directly and/or indirectly related to this primary article to expand their critical review performed.

For this assignment, the written case study report is limited to 5 to 10 pages (double-spaced with 1" margins). In summary, this written case study experience is designed to give students the necessary background and guidance to evaluate a research trial using an established ethical framework.

GROUP PROJECT DISCUSSION:

Each student group (enrolled for a course grade) is required to prepare an oral discussion, with each student responsible for a portion of the in-class presentation. The group should prepare a 1-2 page summary handout of an assigned topic to be distributed to class members. The student group in-class dialogue will be limited to 15 to 20 minutes. Groups should explore recent literature, raising and discussing key ethical concerns, as well as review articles from the Blackboard on-line resources and readings in "Ethical Research in an Ethical Society: Principles, Practicalities, and Politics." Where appropriate, student groups should review the course student videotape for their group topic, as supplementary material is often presented. The students presenting should place an emphasis on the potential implications for current and future IRB Committee review processes.

CLASS PARTICIPATION:

Students are required to attend all four 2-hour class sessions without adversely impacting their grade. Drs. Shroyer and Prochazka will assign a grade for the classroom sessions, worth 10%. The grade assigned for this requirement will be based both on attendance and on the student's active participation in the discussions during class periods, in particular the Group Project Discussion.

*For CLSC 7150 enrollment, there are two required 1.5-hour IRB meetings. Dr. Milgrom will assign a grade for the 10% NJC IRB sessions.

MAKE-UP ASSIGNMENTS:

If you need to miss one class lecture session, then you may write a 5 page paper (double

spaced with 1” margins, including 1 page of references) on a COMIRB 101 case study listed under the Assignments tab in the Blackboard program. This make-up assignment will prevent your grade automatically being lowered due to a missed class session. This assignment is due at the last date of class.

*For CLSC 7150 students needing to make-up an NJC IRB session, Dr. Henry Milgrom has graciously agreed to allow students to attend up to one alternative NJC IRB session. Please contact Dr. Milgrom's secretary at (303) 398-1703 to coordinate your attendance at the make-up session. Thus, she can make a copy of this additional meeting's materials for you. Students needing to miss more than one IRB session and/or more than one class lecture are advised to take the course at a future date.

LATE WORK:
Students are responsible for all information presented in class. Please note, the lectures will cover some materials not found in the textbook and handouts. The Co-Directors are not responsible for providing information related to missed classes. Handouts and/or lecture notes should be obtained from other students in attendance. Missed assignments and extended leave will only be allowed in extremely unusual circumstances (for example, death of a family member).

SPECIAL CONSIDERATIONS:
The Professors will gladly accommodate students with physical disabilities or diagnosed learning disabilities, upon request.

Notebook Readings

- Application for Protocol Review: Sample Application pages for Protocol Review COMIRB 101
- Subject Consent Form for Participation in Clinical Investigation Project
  Sample: "Combined Nortriptyline & Transdermal Nicotine for Smoking Cessation"
- The NEJM Sounding Board article: "Proposed Revisions to the Declaration of Helsinki -- Will They Weaken the Ethical Principles Underlying Human Research"
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research
- "Proposed Standards of Privacy of Individually Identifiable Health Information" - November Federal Register
  with: (1) Letter to President Clinton from A.M.G.A. (2) Email re: Federal Registry rule-making
- NEJM Sounding Board article: "Are Research Ethics Bad for Our Mental Health?"
- NEJM Sounding Board article: "Ethical and Human-Rights Issues in Research on Mental Disorders That
  May Affect Decision-Making Capacity"
- NEJM Sounding Board article: "The Threat to Medical-Records Research"
- Mayo Clinic Proc Article: "Potential Effect of Authorization Bias on Medical Record Research"
- IRB Article: "DNA Banking and Informed Consent - Part 1"
- JAMA Article: "Informed Consent for Genetic Research on Stored Tissue Samples"

- JAMA Article: "Research & Stored Tissues"

- NY Times article: "Drug Trials Hide Conflicts for Doctors"
  Prefaced by ClinTrials Research Inc. promotional blip for trial.

- New York Times article: "Patient or Guinea Pig? Dilemma of Clinical Trials"

- NEJM article: "A Trial of Three Regimens to Prevent Tuberculosis in Ugandan Adults Infected with the
  Human Immunodeficiency Virus"

- Special Issues for Clinical Trials: Plutonium Testing
  Advisory Committee's Part IV Overview and Findings concerning human radiation experimentation.

- NEJM article: "Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1"

- Arch Gen Psychiatry article: "Research With Cognitively Impaired Subjects"

- Code of Federal Regulations: Party 46 Protection of Human Subjects, Revised June 18, 1991

- DHHS Report: Office of Inspector General "Institutional Review Boards: A Time for Reform"

- CITIZEN Comments on HHS Inspector General Report
  Comments by Sidney Wolfe, MD, and Peter Lurie, MD

- USA Today Comments on HHR Inspector General Report
  "Protections found lacking Follow-up report: People in medical studies still at risk."

- JAMA Article: "What Makes Clinical Research Ethical?"